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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,192	06/23/2006	Takayuki Oniki	0171-1287PUS1	3847

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EXAMINER	
SUTTON, DARRYL C	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
03/11/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,192	ONIKI ET AL.	
	Examiner	Art Unit	
	DARRYL C. SUTTON	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed 11/08/2007. New claims 10-22 have been added.

Applicant's arguments filed 09/21/2007 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections an/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7, 10-14, 16 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takeda et al. (US 2001/0007652).

Takeda et al. teach a dentifrice composition for imparting gloss on teeth comprising shellac (Abstract). The composition can be in the form of a gel [0007], [0016]. The content of shellac is 0.01% to 10% [0013]. The composition comprises propylene glycol and/or glycerin [0018]. Thickening agents such as sodium

carboxymethylcellulose are used in the compositions [0017]. Foaming agents such as sodium lauryl sulfate may be included in the composition in amounts of 1.5% by weight [0017] and [0025]. No particular limitation is imposed on the usage of the dentifrice compositions [0019]. Shellac is comprised of jalaric acid and aleuritic acid, i.e. 9,10,16-trihydroxypalmitic acid with ester or lactone linkage.[1]

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such "picking and choosing" within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables, dentifrice forms, gloss agents, foaming agents, conventional dentifrice substances and substances that dissolve shellac, anticipation cannot be found.

That being said, however, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not

[1] Sharma, S.K. et al., Shellac-Structure, Characteristics & Modifications, Def. Sci. J., 1983, p. 262-263.

seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Id. at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients, gel; shellac; sodium lauryl sulfate, carboxymethylcellulose; and propylene glycol or glycerin from within a prior art disclosure, to arrive compositions "yielding no more than one would expect from such an arrangement".

Claims 8, 9, 17, 18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takeda et al. as applied to claims 1-5, 7, 10, 11-14, 16 and 19-21 above, and further in view of Sagel et al. (2003/0219389).

Takeda et al. is discussed above.

Takeda et al. does not teach that the gel composition is applied with a detachable tool.

Sagel et al. teaches tooth whitening products that are comprised of a strip of material and a thin layer of whitening material (Abstract). The whitening composition can be a gel [0041]. The strip is comprised of polyethylene [0053].

Sagel et al. does not teach the whitening agents as defined by instant claim 1.

It would have also been obvious to modify the administration of the composition Takeda et al. to use the polyethylene strip of Sagel since, at the time of the invention, methods of applying oral gel compositions with a strip were known in the art.

Claims 6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapolsky et al. (US 6,103,266) in view of Friedman et al. (US 5,438,076).

Tapolsky et al. teach non water-soluble pharmaceutical carrier gel that adheres to mucosal surfaces providing delivery of pharmaceuticals to surrounding tissues. The gel comprises a non-aqueous solvent and at least one hydroxyalkyl cellulose (Abstract, column 3, lines 45-56). Upon application and adherence to the mucosal surface, the non-aqueous solvent penetrates surrounding tissue and a film is formed (column 4, lines 20-26). Flavoring and plasticizing agents may be used (column 4, lines 51-54). Hydroxyalkylcellulose polymers for use in the invention include hydroxypropyl cellulose; fatty acids such as oleic acid may be used in combination with the cellulose derivative as plasticizing agents to modify the polymer's characteristics (column 6, lines 4-6 and 15-19). The properties of the film *in vivo* are adjusted via the addition of plasticizers (column 8, lines 55-58). The non-aqueous solvents include low alkyl alcohols such as isopropanol (column6, lines 20-24). Pharmaceutical agents which may be used include bactericides and disinfectants (column 6, lines 34-39). Examples of bactericides and disinfectants include chlorohexidine and cetylpyridinium chloride (column 7, lines 6-9). Permeation enhancers include sodium lauryl sulfate (column 8, lines 17-20). The solvent comprises between 50 and 80% by weight of the composition; the film forming

polymer comprises between 4 and 20% by weight; the pharmaceutical agent comprises between 0.1 and 25% by weight; and the permeation enhancer comprises 0 to 3% by weight (column 8, lines 22-43). Upon preparation, the gel may be applied to the treatment site by direct application by finger, swab, or any type of applicator (column 9, lines 7-9).

Tapolsky et al. do not teach a specific embodiment comprised of the whitening agents, dissolvable substances and gelling agents of the instant claims 1 and 3 or the weight percentage of oleic acid.

Friedman et al. teach a composition for treatment or prevention of dental conditions, which forms a solid film upon drying after being topically applied on teeth (Abstract, column 12, lines 9-11 and 48-51). The compositions contain a plasticizer in concentrations of about 1% by weight (column 16, lines 16-19).

Friedman et al. do not teach that the plasiticizer is oleic acid.

At the time of the invention, it would have been obvious to formulate the composition of Tapolsky et al. comprised of hydroxypropylcellulose; oleic acid; isopropanol; chlorohexidine or cetylpyridinium chloride; and sodium lauryl sulfate in the disclosed weight percentages since Tapolsky et al. teaches the incorporation of each component in the invention. Further, since Friedman et al. teach the incorporation of about 1% by weight of plasticizers into oral compositions which form a film on teeth, it would have been within the purview of the skilled artisan to use about 1% by weight of the oleic acid plasticizer in the invention of Tapolsky et al.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612